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10/690,625	10/23/2003	Michel Therin	114138	5931
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OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320			TYSON, MELANIE RUANO	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/690,625

Applicant(s)

THERIN ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/15/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology ("comprising" in lines 2 and 4, and "said" in line 4). Also, "Figure 7" should be removed from the bottom of the abstract. Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

2. Claim 5 is objected to because of the following informalities: it contains the unnecessary term "of". Remove the term "of" from the claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitation "the bulged central part" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 6-7, and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Browning (Publication No. WO 02/078568 A1).

Regarding claim 1, Browning discloses a prosthesis (Figure 8a, not labeled) comprising a porous textile support (20) that includes an arrangement of threads (Figure 7a, element 22), each composed of at least one filament of nonabsorbable polymer material (polyester; page 36, line 1). Figure 7a shows the textile support (20) defines a microporous texture (the blown up portion of Figure 7a shows interstices between the threads at the sites of contact with one another). Browning further discloses a hydrophilic absorbable material (starch or cellulose based hydrogel; page 13, lines 6-10) coats the textile support (page 38, lines 1-2) forming a film enveloping and

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penetrating into the arrangement of threads and occluding the microporous texture (the strands are entirely embedded; page 38, lines 8-10). Figure 8b shows an embodiment where one face remains uncovered (bottom 36; page 38, lines 27-30).

Regarding claim 3, Figure 7a shows the textile support constitutes a two-dimensional structure, since it is a generally flat mesh/net.

Regarding claim 6, Browning discloses one thread (22) comprises several filaments (page 35, lines 17-19) of nonabsorbable polymer material (polyester; page 36, line 1), and the blown-up portion of Figure 7 shows the microporous texture additionally comprises interstices (pores 28) between filaments of the same thread (22).

Regarding claim 7, Browning discloses the protected zone (the area covered by the absorbable coating 32) has a surface completely covering the textile support (outer surface of the mesh is covered entirely by the absorbable coating; page 38, lines 10-11).

Regarding claim 14, Browning discloses the absorbable coating (32) is chosen from the group formed by collagens, polysaccharides, and their mixtures (starch or cellulose based hydrogel; page 13, lines 6-10).

Regarding claim 15, Browning discloses the tissue structure is an extraperitoneal tissue since the prosthesis is used to repair hernias, including bladder protrusion (page 6, lines 13-15 and page 1, lines 9-22).

Regarding claim 16, Figure 7a shows the arrangement of threads (22) constitutes a knitted structure (20).

Regarding claim 17, the blown up portion of Figure 7a shows interstices between the threads (22) at the sites of contact with one another, thus belonging to the meshes of the knitted structure (20).

Regarding claim 18, Figure 7a shows empty spaces (a) defined between threads (22) away from their sites of contact, thus makeup the intermesh spaces of the knitted structure (20).

6. Claims 19 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Ory et al. (Patent No. 6,451,032 B1)

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 19, Ory et al. disclose a process for preparing a composite prosthesis (Figure 1, element 1) comprising the steps of preparing a solution of a hydrophilic absorbable material (collagen and a hydrophilic additive; column 4, lines 18-25), inherently in the fluid or liquid state since Ory et al. disclose the material is spread over the support (column 6, line 42), and then is cooled to allow for solidification (gelled by cooling; column 6, lines 54-55). Ory et al. also disclose a porous textile support (column 3, lines 55-56) comprising an arrangement of threads (yarn; column 3, lines 57-

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58) each composed of at least one filament of nonabsorbable polymer material (polyester; column 5, lines 66-67). Furthermore, the porous textile support (not labeled) is impregnated with the solution since the pores (or interstices that make up the "microporous" texture) of the textile support inherently soak up the solution as it is applied (column 6, line 45). Ory et al. further discloses drying the impregnated part of the textile support (column 6, lines 62-63).

Regarding claim 23, Ory et al. disclose a reinforcement prosthesis (column 2, lines 28-31); therefore, a reinforcement prosthesis is obtainable by the process as described above.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. Claims 2, 8, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning in view of Brown et al. (Publication No. US 2003/0023316 A1).

Regarding claim 2, Browning discloses a prosthesis as claimed above, wherein the textile support (Figure 8a, element 20) defines a macroporous texture (Figure 7a), comprising volumes whose surface is defined by the empty spaces (a) between threads (22) away from their sites of contact, and whose height (not shown) is defined by the thickness of the textile support (20). Regarding claim 12, Browning discloses that the absorbable coating may be applied to one side of the support (top or bottom; page 38, lines 27-32). Therefore, it is obvious the film occludes the macroporosity (holes between non-contacting threads) of the textile support over at least part of the surface (or "zone"). Regarding claim 13, Browning discloses that the absorbable coating (32) may be applied to both sides of the support (top and bottom) so that the support is encased and has no holes or gaps on either side (page 38, lines 13-17). Therefore, it is obvious the coating occludes the macroporosity (holes between non-contacting threads) of the support (20) over the whole surface (or "zone").

Browning et al. does not disclose a noncontinuous absorbable material. Like Browning, Brown et al. disclose a prosthesis (Figure 1, element 10). Unlike Browning, Brown et al. disclose the film of absorbable material (small intestine submucosa; 12) is noncontinuous and preserves the macroporous texture of the textile support, since it does not cover the entire support (outer edges 30 of the support are devoid of absorbable material, therefore, the spaces between the threads 28, or the



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“macroporous texture” at the outer edges 30 is preserved). This configuration allows a portion of the prosthesis to act as a scaffold for tissue ingrowth and remodeling, while the macroporous texture portion provides additional mechanical strength to the support (paragraph 48). Therefore, to construct the prosthesis of Browning wherein the macroporosity texture of the support is preserved as taught by Brown et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to promote tissue ingrowth while providing additional mechanical strength.

Regarding claim 8, Browning et al. does not disclose the textile support has the shape of a rectangular part and the protected zone extends along a central band of the part. Brown et al. disclose the part may be rectangular (Figure 1), wherein the protected zone (from the first end 20, including sides 24, through the second end 22) represents a central band of the part, since it is a strip through the center of the part. This configuration allows a portion of the prosthesis to act as a scaffold for tissue ingrowth and remodeling, while the macroporous texture portion provides additional mechanical strength to the support (paragraph 48). Therefore, to construct the prosthesis of Browning wherein the macroporosity texture of the support is preserved as taught by Brown et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to promote tissue ingrowth while providing additional mechanical strength.

10. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning in view of Ory et al.

Regarding claim 4, Browning discloses a prosthesis as claimed above, however, Browning does not disclose the film has a thickness of less than or equal to 500 microns. Like Browning, Ory et al. disclose a prosthesis (Figure 1, element 1) having a hydrophilic absorbable film with a thickness between approximately 30 microns and 100 microns. This configuration helps the prosthesis to prevent postsurgical adhesions in the treatment of eventrations and hernias (column 2, lines 35-48). Therefore, to construct the prosthesis of Browning, wherein the film has a thickness of less than or equal to 500 microns as taught by Ory et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to help prevent postsurgical adhesions.

Regarding claim 5, Browning in view of Ory et al. do not disclose the film has a thickness of 10 to 100 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct a prosthesis where the film has a thickness of 10 to 100 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

11. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Browning.

Regarding claim 9, Browning discloses a prosthesis as claimed above, where the central portion of the prosthesis is protected (i.e. coated with absorbable material); however, Browning does not disclose the prosthesis is in the shape of a strip with parallel edges. Regarding claim 10, Browning does not disclose the parallel edges are

curved in an arch. Browning discloses the prosthesis may have any shape or size and may be cut to the appropriate dimensions as required by the user (page 37, lines 7-9). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the prosthesis in the shape of a strip with parallel edges.

Applicant has not disclosed that a strip with parallel edges provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with parallel edges or any other shape (for example, where the parallel edges are curved in an arch) because the function of the prosthesis is to act as a reinforcement for tissue structures and this function is not affected by its shape. Therefore, it would have been obvious to modify the prosthesis of Browning to obtain the invention as claimed in claims 9 and 10.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Browning in view of Brown et al., further in view of Landgrebe et al. (EP 0774240 A1).

Browning discloses a prosthesis as described above, however, Browning does not disclose the prosthesis is in the shape of a strip with nonparallel edges, the bulged central part being a protected zone and the narrower lateral parts being nonprotected. Brown et al. disclose a prosthesis where the hydrophilic absorbable material (Figure 1, element 12) partially covers the support (from a first end 20 to a second end 22) and leaves the ends of the support (30) free from any coating (unprotected). This configuration allows a portion of the prosthesis to act as a scaffold for tissue ingrowth and remodeling, while the unprotected portion provides additional mechanical strength

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to the support (paragraph 48). Therefore, to construct the prosthesis of Browning where the lateral parts (or end portions) are nonprotected would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a prosthesis that promotes tissue ingrowth and remodeling while providing additional mechanical strength.

Browning et al. in view of Brown et al. do not disclose a strip with nonparallel edges. Landgrebe et al. disclose a strip (Figure 1, not labeled) having nonparallel edges (top edge 2 and bottom edge not labeled). Figure 1 shows the device is bulged in the central region (1) and narrower at the ends (5, 6, 7, and 8). This configuration allows the device to support a wide surface area of an organ (bladder; column 1, lines 45-47), thus contributing to a reliable treatment of incontinence in cases of extreme weakness of the pelvic floor with prolapsing anatomical displacement of the organs of the lesser pelvis (column 1, lines 33-39). Therefore, to construct the strip of Browning et al. in view of Brown et al. having nonparallel edges and a bulge as taught by Landgrebe et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to support prolapsed structures on a large surface area.

13. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ory et al.

Regarding claim 20, Ory et al. do not disclose the impregnation step is done by immersing the surface of the textile support in the solution. Regarding claim 21, Ory et al. do not disclose the impregnation step is done by spraying the solution on to the surface of the textile support. Ory et al. disclose the coating is spread uniformly over the

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textile support (column 6, line 45), thus impregnating with the solution, since the pores (or interstices that make up the "microporous" texture) of the textile support soak up the solution as it is applied. It is well known in the art to use the methods claimed above. Furthermore, applicant has not disclosed that the methods of immersing or spraying the textile support with the solution provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well if immersed or sprayed because the function of the process is to impregnate the textile support and this function is not affected by method since the textile support is porous. Therefore, it would have been obvious to modify the impregnation step of Ory et al. to obtain the invention as claimed in claims 20 and 21.

Regarding claim 22, Ory et al. do not disclose the viscosity of the solution. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a solution having a viscosity of less than or equal to 1000 centipoises, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-3, 6, 8-14, and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/690532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are more specific and add features. The structural limitations set forth in claims 1-3, 6, 8-14, and 16-18 of the instant application are also claimed in the copending application, e.g., a porous textile support, an arrangement of threads, at least one filament composed of nonabsorbable polymer material, a hydrophilic absorbable material covering the textile support.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 4-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/690532 in view of Ory et al. The difference between claims 4-5 of the instant application and claim 1 of the copending application is the thickness of the film. Ory et al. teaches the thickness of the film is between approximately 30 microns and 100

microns. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the thickness of the film as taught by Ory et al. in order to help prevent postsurgical adhesions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claim 7 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/690532 in view of Browning. The difference between claim 7 of the instant application and claim 1 of the copending application is that the protected zone has a surface completely covering that of the textile support. Browning teaches the absorbable material coats the entire surface of the textile support. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthesis having a protected zone with a surface that completely covers the textile support as taught by Browning, in order to make the prosthesis less susceptible to bacteria and easier to handle during implantation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson   
August 3, 2006

  
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8/7/06